1655 #

Docket No. 20239-706

Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):

[X] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington .D.C. 20231.

[ ] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner _____ at Facsimile No. _____ at ____a.m./p.m.

Dated: September 29, 2000 Name of Person Certifying: _____
Printed Name :Leslie Hoffmann

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Klaus PFEFFER, et al.	Assignee:	Bavarian Nordic
Filing Date:	January 26, 2000	Examiner:	J. Einsmann
Serial No.:	09/403,690	Group Art Unit:	1655
Title:	TAQMAN TM-PCR FOR THE DETECTION OF PATHOGENIC E. COLI STRAINS		

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE & FEE TRANSMITTAL

Sir:

In response to the Restriction Requirement mailed on June 29, 2000, enclosed herewith for filing are the following:

- ☐ A Response/Amendment [ ] page(s)
- ☒ A Response to Restriction Requirement under 35 USC 121 [5] page(s)
- ☐ An Amendment Under 37 CFR § 1.111 [ ] page(s)
- ☐ An Amendment Under 37 CFR § 1.116 [ ] page(s)
- ☐ Other _____ [ ] page(s)

Also included are:

- ☒ A Petition for Extension of Time [2] months [ ] page(s)
- ☐ Information Disclosure Statement
  [ ] page(s) of PTO-1449 [ ] copies of IDS citations
- ☐ Verified Statement of Small Entity Status under 37 CFR § 1.27
  ☐ attached hereto ☐ was previously filed
- ☐ Other: _____
- ☒ Return Postcard

Fee Calculation						
☒ The following fees are submitted:						CALCULATIONS
EXTRA CLAIMS FEE				OTHER THAN SMALL ENTITY	SMALL ENTITY	$
CLAIMS	CURRENT #	# OF CLAIMS PREVIOUSLY PAID	# EXTRA	RATE	RATE	
Total Claims	–			× $18.00	× $9.00	$
Independent claims	–			× $80.00	× $40.00	$
MULTIPLE DEPENDENT CLAIM(S)						
☐ Yes ☐ No				$270.00	$135.00	$
Petition for Extension of Time Fee (2 months)						$390.00
OTHER FEES _____ *(specify)*						$
					TOTAL FEES =	$390.00

☒ Conditional Petition for Extension of Time: An extension of time is requested to provide for timely filing if an extension of time is still required after all papers filed with this communication have been considered.

☐ A check in the amount of $ _____ to cover the above fees is enclosed.

☒ Please charge Deposit Account No. 50-1189, Docket No. 20239-706, in the amount of $390.00 to cover the above-fees. *A duplicate copy of this sheet is enclosed.*

☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1189, Docket No. 20239-706. *A duplicate copy of this sheet is enclosed.*

Respectfully submitted,

By: _____

Carol M. Gruppi
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Date: September 29, 2000

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Docket No.: 20239-

Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a))			
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[x]	deposited with the United States Postal Service as First Class Mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.	[ ]	transmitted by facsimile to the Patent and Trademark Office.
Date: September 29, 2000		Name of Person Certifying: Leslie Hoffmann	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Klaus Pfeffer	Assignee:	Bavarian Nordic
Serial No.:	09/403,690	Examiner:	J. Einsmann
Filing Date:	January 26, 2000	Group Art Unit:	1655

Title: Taqman ™-PCR For the Detection of Pathogenic E. Coli Strains

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. § 121

This is in response to the Office Action dated June 29, 2000. This response is accompanied by a petition for a two month extension of time to extend the period to respond to the Office Action to September 29, 2000, and the appropriate fee under 37 C.F.R. § 1.16 and § 1.17. Accordingly this response is timely filed.

In the Restriction Requirement set forth in the Office Action mailed June 29, 2000, the Examiner stated that the application contains claims to more than one species of the generic invention and required Applicants to elect a patentably distinct species for prosecution on the merits. The patentably distinct species provided in the Office Action were as follows:

(A) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and obligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of a gene encoding enterotoxigenic E. coli heat labile toxin. Preferred

embodiments include methods which employ oligonucleotide primers oligonucleotide primers with SEQ ID NOS.:1 and 2 or using oligonucleotide primers SEQ ID NO.:1 and 2 in combination with oligonucleotide probe SEQ ID NO.:19 wherein the oligonucleotide primers/probes are specific for a gene encoding enterotoxigenic E. coli heat labile toxin;

(B) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of a gene encoding enterotoxigenic E. coli heat labile toxin. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NOS.:3 and 4 or using oligonucleotide primers SEQ ID NOS.:3 and 4 in combination with oligonucleotide probe SEQ ID NO.:20 wherein the oligonucleotide primers/probes are specific for a gene encoding enterotoxigenic E. coli heat stable toxin;

(C) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of a gene encoding enteraggregative E. coli heat labile toxin. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NOS.:5 and 6 or using oligonucleotide primers SEQ ID NOS.:5 and 6 in combination with oligonucleotide probe SEQ ID NO.:21 wherein the oligonucleotide primers/probes are specific for a gene encoding enteroaggregative E. coli heat stabile toxin;

(D) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of pCVD432 plasmid for amplification of a DNA encoding sequence characteristic for enteroaggregative erotoxigenic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NOS.:7 and 8 or using oligonucleotide primers SEQ ID NOS.:7 and 8 in combination with oligonucleotide probe SEQ ID NO.:22 wherein the oligonucleotide primers/probes are specific for the pCVD432 plasmid for amplification of a DNA sequence characteristic for enteroaggregative E. coli;

(E) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of the inv-plasmid for amplification of a DNA sequence contained in

enteroinvasive E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NOS.:9 and 10 or using oligonucleotide primers SEQ ID NOS.:9 and 10 in combination with oligonucleotide probe SEQ ID NO.:23 wherein the oligonucleotide primers/probes are specific for the inv plasmid for amplification of a DNA sequence contained in enteroinvasive E. coli;

(F) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of EAF plasmid for amplification of a DNA sequence characteristic for enteropathogenic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NOS.:11 and 12 or using oligonucleotide primers SEQ ID NOS.:11 and 12 in combination with oligonucleotide probe SEQ ID NO.:24 wherein the oligonucleotide primers/probes are specific for EAF plasmid for amplification of a DNA sequence characteristic for enteropathogenic E. coli;

(G) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of the eae a gene for amplification of a DNA sequence characteristic for enteropathogenic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NOS.:13 and 14 or using oligonucleotide primers SEQ ID NOS.:13 and 14 (please note, the Restriction Requirement recites only SEQ ID NO.:3 here, we are in the process of confirming that this is a typographical error with the Examiner) in combination with oligonucleotide probe SEQ ID NO.:25 wherein the oligonucleotide primers/probes are specific for eae gene for amplification of a DNA sequence characteristic for enteropathogenic E. coli;

(H) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of the gene encoding shiga-like toxin sltI for amplification of a DNA sequence characteristic for enterhemorrhagic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NOS.:15 and 16 or using oligonucleotide primers SEQ ID NOS.:15 and 16 in combination with oligonucleotide probe SEQ ID NO.:26 wherein the

oligonucleotide primers/probes are specific for the gene encoding shiga-like toxin sltI for amplification of a DNA sequence characteristic for enterohemorrhagic E. coli; and

(I) Claims 2-3, 6-7, 11-12, and 14-15 (all partially). Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of the gene encoding shiga-like toxin sltI for amplification of a DNA sequence characteristic for enterhemorrhagic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NOS.:17 and 18 or using oligonucleotide primers SEQ ID NOS.:17 and 18 in combination with oligonucleotide probe SEQ ID NO.:27 wherein the oligonucleotide primers/probes are specific for the gene encoding shiga-like toxin sltII for amplification of a DNA sequence characteristic for enterohemorrhagic E. coli.

Applicants hereby provisionally elect the species in Group A for prosecution on the merits. The Examiner has stated that claims 1, 4-5, 8-10, 13, and 16-20 are generic. The claims readable on this species are 1, 2-3, 4-5, 6-7, 8-10, 11-12, 13, 14-15, and 16-20. Applicants, however, traverse the Restriction Requirement on the basis that it would not be unduly burdensome for the Examiner to search more than one patentably distinct species.

A Restriction Requirement requires the inventions be independent or distinct as claimed, and there must be a serious burden on the Examiner for restriction to be required (*see* MPEP § 803). Ten independent and distinct nucleotide sequences have been determined to be a "reasonable number" of sequences to be claimed and examined in a single application without restriction (*see* MPEP § 803.04). Thus, examination of ten independent and distinct nucleotide sequences has been determined not constitute an undue burden for the Examiner (*see* MPEP § 803.04).

Likewise, Applicants submit that it would not be unduly burdensome for the Examiner to search for more than one set of primers within the context of the claimed subject matter. Accordingly, reconsideration of the Restriction Requirement is respectfully requested. If

Examiner has any questions concerning this Response, the Examiner is respectfully requested to telephone Applicant's agent at the telephone number given below.

A fee of $390.00 is due under 37 C.F.R. § 1.16 and § 1.17 for the Petition for a Two Month Extension of Time filed concurrently herewith. The Assistant Commissioner is hereby authorized to charge any additional fees which may be required by this paper, or credit any overpayment to Deposit Account No. 50-1189. Docket No.: 20239-706. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

By: _____

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Date: September 29, 2000

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